EXHIBIT C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

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IN RE: ETHICON, INC.	*	MASTER FILE NO.
PELVIC REPAIR SYSTEM	*	2:21-MD-02327
PRODUCTS LIABILITY	*	MDL 237
LITIGATION	*	

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DEPOSITION OF NEERAJ KOHLI, M.D.

CROWNE PLAZA HOTEL

320 Washington Street

Boston, Massachusetts

March 21, 2016 1:13 p.m.

Maryellen Coughlin, RPR/CRR

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Q. Right.
A. That is part of my expert report.
(Whereupon, Deposition Exhibit 3, Expert report of Dr. Kohli, was marked for identification.)
Q. (BY MS. GUILFOYLE) Okay. So your expert report which actually I'll show you which is marked as Exhibit 3.
A. Yes.
Q. And that's near the end of your expert report you have a list of cases?
A. Correct.
Q. And is that a fair and accurate representation of all the cases in which you've given either deposition or trial testimony in the past four years?
A. Yes.
Q. Okay. There are no cases missing from that?
A. To my knowledge. I don't believe so.
Q. Do you keep a list of cases in which you've given trial or deposition testimony, Doctor?
A. I don't. What I usually do is I

usually search my calendar, and usually it will say trial or deposition, and that's what I usually use.

Q. So if you were deposed, for example, in 2015, you would remember that, right?

A. Right.

Q. And having reviewed the list of cases, you believe that's fair and accurate?

A. I believe so, yes.

Q. What about number 7, graphics, testing, recordings, spreadsheets?

A. I have none of those.

Q. Category 8?

A. I have none of those.

Q. And number 9, is it fair to say that's what been marked as Exhibit 3 is a fair and accurate copy of your final report?

A. It is.

Q. Category number 10?

A. I have none of those.

Q. Number 11?

A. Testing done by me. I have done no testing.

Q. Okay.

A. Again, no testing for number 12.

Q. 13?
A. We have no plaintiff in this case.
Q. Right. 14, communications reflecting.
A. I've had no communication with any other experts.
Q. Okay.
A. Again, 15 --
Q. Right, is on the thumb drive.
A. Thumb drive.
Q. Okay.
A. 16, all of my opinions are supported with the literature in reference on my Rule 26.
Q. Okay. Do you have copies of any of your deposition transcripts at your office or elsewhere?
A. From previous trials?
Q. Right.
A. I do.
Q. Okay. And do you maintain those in a certain file?
A. They're either maintained in a certain file or they're part of a e-mail trail with the lawyers. Some of them I --

pelvic surgery.

Q. Do you currently implant mesh?

A. Yes.

Q. And when did you first start to implant mesh?

A. That would probably be during my training.

Q. Okay. As a resident?

A. As a resident, we would do some slings. The traditional techniques of slings because minimally invasive midurethral slings weren't there then.

Q. Okay.

A. But also during my fellowship we did a lot of sacral colpopexies as an open approach, so we did implant mesh during that time period as well.

Q. Do you currently implant any midurethral slings?

A. Yes.

Q. Do you -- what type of slings do you implant?

A. Although I have done many in the past, currently we do only retropubic suburethral slings.

Q. And how long have you been -- limited your sling practice to retropubic?

A. I would have to guess. Probably the last five, six years.

Q. And is there a particular manufacturer or brand sling that you implant?

A. We currently use the Gynecare TVT at one of our hospitals, and I use the Boston Scientific Prolift -- I'm sorry. Advantage Fit at one of our other hospitals.

Q. And how many times per month or per year if it's easier would you estimate you implant a suburethral sling?

A. I'm probably doing anywhere from 15 to 25 slings a month.

Q. And that would be any combination of those two manufacturers?

A. Yes.

Q. And those slings are both made out of polypropylene mesh, correct?

MR. ORENT: Objection.

A. Yes.

Q. Was there a certain period of time, Doctor, if any, when you implanted the TVT-O?

A. Yes.

Q. Okay. And during what time frame did you implant the TVT-O for?

A. I think we -- and again, this is just based on my recollection. The first two or three years after TVT-O was introduced, which I believe was in 2003, 2004, we were implanting TVT-O at that point and then stopped thereafter.

Q. So roughly 2003, 2004 to 2006?

A. Yeah, 2005, 2006.

Q. And when you were implanting the TVT-O sling, do you have an estimate as to how many times per month on average you implanted that sling?

A. I don't have an estimate on how many times per month, but I would say that I've probably done between 50 and 100 TVT-O slings.

Q. Total?

A. Total.

Q. And do you record that information anywhere? Would that be something that you could go back and look at to get the exact number or not?

A. So one of the problems has been is that in the last 15 years I've gone from one hospital system to another to another, and

developed, trialed, researched, taught, and so I know that there was talk of us also being involved in the Prolift and being involved in the teaching and training of that procedure, but that was another procedure that I didn't feel comfortable with. So it wasn't the availability of compensation or teaching opportunities. It was more my own apprehension and anxiety about the procedures.

Q. Okay. Did you -- but it's fair to say that you stopped receiving compensation from Ethicon and Gynecare?

A. Well, when I stopped using the product, there was no preceptorships to be done if I wasn't using the product, so that is a true statement.

Q. Okay. Is it your testimony that because you decided to stop using the product that was why you stopped being retained as a preceptor or hired as a preceptor?

MR. ORENT: Objection.

A. Yes.

Q. Do you agree that one of the goals of a urogynecologist is to advance the care of women?

MR. ORENT: Objection.

A. I think that's a very vague question, and the reason being is that not all advancements are good, safe or effective. I think some advancements are better for patients in terms of safety, efficacy outcomes, and there are some advancements that aren't, and I think part of our job as clinicians is to do what's best for our patients and do no harm and be critical about technology and advancements in medicine, and sometimes wait for appropriate data before we decide to either go further or to adopt or not adopt any advancement that's proposed.

Q. Did you ever participate in any clinical trials for the TVT-O?

A. I can't remember, and I don't think we did.

Q. I certainly will defer to you to look at your resume. I can tell you that I did not see any mention of that.

A. Yeah, I don't think we did any clinical trials of the TVT-O.

Q. Okay. Did you ever participate in any peer-reviewed studies on the use of the TVT-O?

A. Let's see here. I don't believe we did. Yeah, I don't think we've written, again, any peer-reviewed studies analyzing the TVT-O.

Q. Are you familiar with other studies that have been peer reviewed analyzing the TVT-O?

A. Yes.

Q. Are you familiar with other studies involving like mata-analyses?

A. Yes.

Q. Do you know what the term mata-analyses means?

A. Meta-analyses?

Q. Meta.

A. Yes.

Q. What does that mean, Doctor?

A. It essentially means looking at a series of different papers that have been done and pooling that data and doing an analysis of that data in order to increase sample size as well as the number of operators or physicians presenting that data.

Q. And do you rely on those in your practice, Doctor?

A. We rely on a variety of information, clinical research, meta-analyses,

personal experience, but that would be one of the components of something we would look at in terms of data?

Q. As far as like starting with what you consider the most reliable; is that a clinical trial?

MR. ORENT: Objection.

A. And again, there are different types of research that are graded as far as levels of evidence. The literature talks about Level I evidence being a randomized prospective controlled trial.

Q. Mm-hmm.

A. Typically the randomization is typically key. So Level II data would be a prospective trial with a cohort or case control, but it's not randomized.

Q. Mm-hmm.

A. Level III data would be more retrospective with again a case control. And Level IV data would be more of a case series which is more of an observational study.

Q. Okay.

A. A meta-analysis can be categorized as Level I or Level II depending on the types of

(Whereupon, Deposition Exhibit 10, 3/1/12 Deposition of Dr. Kohli was marked for identification.)

Q. (BY MS. GUILFOYLE) Doctor, you have before you what's marked as Exhibit 10, and I will represent to you that is testimony, deposition testimony, from the Scott versus Bard case. And if I could ask you to turn to page 17 and in particular line 27.

MR. ORENT: There's no line 27 on 17.

MS. GUILFOYLE: Can we go off the record for a minute.

(A break was taken.)

(Whereupon, Deposition Exhibit 11, Trial testimony of Dr. Kohli, was marked for identification.)

Q. (BY MS. GUILFOYLE) I'm going to show you, Doctor, what was marked as Exhibit 11.

A. Okay.

Q. I'll represent to you that's a rough draft of trial testimony by you in the Scott case. Have you seen that before?

A. I don't recall if I've seen it.

Q. Okay. If I could direct your

attention to page 17, and if you could read to yourself the question and then read out loud the answer. Actually I'll -- yeah. Are you ready?

A. I'm on page 17.

Q. Okay. So on 22 is the question.

A. Would you like me to read it?

Q. Yeah.

A. "The Jury has heard that the pelvic organ prolapse kits particularly Avaulta Plus made of polypropylene are the slings and the TVT procedure you were discussing earlier are they made of polypropylene mesh, too?"

Q. And then your answer, Doctor?

A. "Polypropylene has slowly filtered out to us to be the safest style of synthetic mesh we can use. We have used a variety of synthetic meshes. Artificial meshes in the pelvis and for general surgery over the last 50 to 60 years the first nylon mesh was first described in 1956 so we have had 50 years of experience with synthetic materials over time as we become smarter as tissue engineering has become more coordinated with the medicine we realize that certain materials are safer. Certain weaves are safer. Certain structures are

safer and currently the general thinking across our society and our leadership out of all the artificial materials polypropylene is probably the safest."

Q. Okay, thank you. So that was accurate testimony when you gave it at trial under oath, correct?

A. Yes.

Q. Now, one of the opinions that you set forth in your report, Doctor, is that there is a safer alternative to the use of the TVT-O, correct?

A. Yes.

Q. Okay. And what is it that you rely on for your opinion?

A. Well, I rely on my own clinical experience and my history of taking care of patients as well as some of the literature I've reviewed and books I've read and discussions I've had with colleagues and physicians.

Q. And the safer alternatives that you recommend are in part non-mesh procedures?

A. Well, I think there's a variety of safer alternatives for incontinence, including non-mesh procedures which we talked about, Burch

colposuspension, autologous slings, even the needle suspension procedures which might be safer. I also think that the retropubic TVT is probably a safer procedure as well.

Q. Isn't it true if we're talking about the Burch procedure and autologous -- did I pronounce that right?

A. Autologous.

Q. -- autologous slings that those aren't always an option for an individual patient?

A. I don't know if you would clarify which patients they're not an option for. It really depends on the surgeon's experience. It depends on their skill set. The current group of surgeons who are currently practicing urogynecology there's a generational gap where they haven't done Burchs. So clearly if they were to recommend a Burch now to a patient, that might be risky in the sense that they don't have experience or expertise doing that procedure.

Q. But when you do the Burch procedure, don't you have to harvest tissue from elsewhere in the body?

A. No, that is the sling procedure.

The Burch procedure is actually a series of sutures which are placed in the pubocervical fascia and the periurethral tissue which anchors that tissue to the Cooper's ligament.

Q. But the autologous sling is you harvest tissue --

A. So the sling procedure --

Q. -- is that correct?

A. In the autologous sling, correct, but there are other sling procedures that can use biologic materials where you wouldn't have to harvest.

Q. Okay. And these require additional incisions and invasiveness, correct?

MR. ORENT: Objection.

A. It depends on your technique and what material you're using. Oftentimes you can do it through the small incision that you make for the sling if you're using rectus fascia. Some people use vaginal wall, and you can do it through the same vaginal incision you're doing. So depending on the technique and what material you're using, it may or may not require a separate incision or longer operative time.

Q. Isn't it true, Doctor, that the

expert.

Q. Have you worked for the FDA?

A. I have not worked for the FDA.

Q. Have you studied the regulatory rules for submission of any kind of documents by a medical device manufacturer to the FDA?

A. I serve as chief medical officer for a company called ME Medical, and over the last two years we have developed, designed and manufactured a urinary catheter in the area of urogynecology, and as part of that process, we were involved in submitting to the FDA, and I was involved in that.

Q. Okay. Were you submitting it as a predicate device, Doctor?

A. It's submitted as a predicate device based on a urinary catheter.

Q. Okay. And you did that on your own without any legal counsel? Is that your position?

A. Oh, no. I just said that we did it as part of my involvement as chief medical officer. We had significant input from the rest of the management team as well as legal counsel as needed.

Q. Okay. And you'd agree with me that the mesh used in the TVT and the TVT-O is the same, correct?

MR. ORENT: Objection.

A. Yes.

Q. And you'd also agree with me that the only thing that remains in the body following insertion is the mesh, correct?

A. Yes.

Q. In both products?

A. Yes.

Q. What factual evidence do you have to state -- to support your opinion that this was not a proper predicate device?

A. Well, my statement was that they share little clinical resemblance.

Q. Okay. So you're not challenging --

A. So I can't comment on that.

Q. -- whether or not it was an appropriate predicate device?

MR. ORENT: Objection, misstates his testimony.

Q. Is that what you're saying?

A. I'm not challenging the ruling of the FDA. I'm challenging that their argument

that this was very similar between the two is like saying that a car and a bicycle with training wheels both have four wheels and they both are used to go from Point A to Point B, but that doesn't mean that both of them are similar or that I would put an 8-year-old in a car. And so my feeling was is that they did not have significant clinical resemblance, exactly how I state it.

Q. Okay. What evidence do you have, Doctor, to support your position that the TVT-O is a defective design?

A. Again, we discussed this previously, and I do talk about specifics of this which are based on my clinical experience, my teaching for Gynecare, my review of the literature as well as the review of internal Gynecare documents. It's blind insertion of a permanent device through the transobturator space which is a space that many surgeons and gynecologists and urogynecologists previously did not have a lot of familiarity with. My issue really is placement of a polypropylene mesh which is a permanent material which can cause fibrosis, contraction, scarring through a space which has

17-year study is not sufficient to offer an opinion as to the safety and efficacy of a medical device?

MR. ORENT: Objection.

A. Again, I think you're misquoting me. I said that we have --

Q. I'm asking you this question then.

A. No. I think a 17-year study is amazing in terms of longitudinal follow-up, and we have that for TVT. But you asked me that isn't it your opinion that TVT-O is as efficacious as a TVT, and my response was is that I can't tell you that because I have 17-year data for a TVT, and I don't have anything close to that for a TVT-O.

Q. So how much data do you need for the TVT-O before you would make that opinion?

MR. ORENT: Objection.

A. Well, if you're comparing two products, I would think that you would have to have comparative data. To compare the efficacy of one procedure at 5 years to the efficacy of another procedure at 17 years just seems flawed in my case.

Q. So are you saying that in order to

compare the efficacy of the TVT to the TVT-O we have to wait until the TVT-O has been on the market for 17 years?

A. What I'm saying is that I can't tell you --

Q. I just want you to answer that question.

MR. ORENT: Objection.

A. Yes.

Q. Okay. Have you ever had done any meta-analyses yourself?

A. Not a meta-analyses per se. We have done reviews of the literature when we're doing review papers where we look at the different reviews and we may actually put them in a tabular format. But in terms of doing a statistical analysis pooling the meta-analyses, no.

Q. Would you consider yourself qualified to do that?

A. Again, my clinical expertise is not in statistics. I would most likely be talking to a statistician to help develop those analyses.

Q. Would you agree that a randomized clinical trial is one of the most effective ways

to evaluate a medical device?

MR. ORENT: Objection.

A. I think given its limitations, although there are limitations to it, it is probably considered Level I data comparative to other types of studies.

Q. All right.

(Whereupon, Deposition Exhibit 13, Effectiveness and complication rates of tension-free vaginal tape-obturator in the treatment of female stress urinary incontinence in a medium- to long-term follow up by Pan-Fen Tan, et al, was marked for identification.)

Q. (BY MS. GUILFOYLE) Doctor, I'm going to show you what's been marked as Exhibit 13 for this deposition --

A. Thank you.

Q. -- and ask you if you've ever seen this article before.

A. I believe I have.

Q. Was that in fact one of the articles that you relied on in conjunction with forming your opinions?

A. Yes.

C E R T I F I C A T E

I, Maryellen Coughlin, RPR/CRR and notary public in the Commonwealth of Massachusetts, do hereby certify that the foregoing is a true and accurate transcript of my stenographic notes of the deposition of NEERAJ KOHLI, M.D., who appeared before me, satisfactorily identified himself, and was by me duly sworn, taken at the place and on the date hereinbefore set forth.

I further certify that I am neither attorney nor counsel for, nor related to or employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action.

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING REPORTER.

Maryellen Coughlin

MARYELLEN COUGHLIN, RPR/CRR